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BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Mary L.Verstynen
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587
Telephone: (574) 267-6639 extension 1343
Fax: (574) 372-1683

Proprietary Name: LactoScrew™ Screw Anchor

Common Name: resorbable screw anchor

Classification Name: Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Resorbable Screw Anchor, K012872

Device Description:
This device is a screw anchor used to provide a means for attaching soft tissue to bone during healing. The device consists of a screw portion and a head portion. The screw portion engages the bone while the head portion provides a means to drive the anchor in and a means to attach the suture to the anchor. These anchors are comprised of 85% L-Lactide/15% Glycolide and are available in 3.5 mm and 5.5 mm diameter sizes.

Intended Use:
Indications for the LactoScrew™ Screw Anchors include use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications are as follows:

Shoulder: Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tendodesis, deltoid repair.
Wrist/Hand: Scapholunate ligament reconstruction, ulnar/radial collateral ligament reconstruction.
Ankle/Foot: Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, halluxvalgus reconstruction, mid- and forefoot reconstruction.
Elbow: Tennis elbow repair, ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction.
Knee: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tendodesis, and patellar ligament/ tendon repair.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639

FAX
574.267.8137

E-MAIL
biomet@biomet.com

Knee: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tendodesis, and patellar ligament/ tendon repair.

Summary of Technologies: The LactoScrew™ Screw Anchors technological Characteristics (material and design) are similar to the predicate devices.

Non-Clinical Testing: Mechanical testing was performed to establish substantial equivalence to the predicate devices.

Clinical Testing: Clinical testing was not used to establish substantial equivalence to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2004

Ms. Mary L. Verstynen
Biomet Orthopedics Incorporated
56 East Bell Drive
PO Box 587
Warsaw, Indiana 46581-0587

Re: K033355
Trade Name: LactoScrew™ Screw Anchor
Regulation Number: 888.3040
Regulation Name: Smooth or metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MAI
Dated: April 5, 2004
Received: April 6, 2004

Dear Ms. Verstynen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033355

Device Name: LactoScrew™ Screw Anchor

Indications For Use:

Indications for the LactoScrew™ Screw Anchor include use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications are as follows:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Prescription Use X
(Per 21 CFR 801.109)

Over-The-Counter Use

(Optional Format 1-2-96)

510(k) Number K033355